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INCORPORATED

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**ENZYMATIC THERAPY®
&
PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328
P: 920.469.1313 ♦ F: 888.570.6460 (Enzymatic)
P: 920.469.9099 ♦ F: 920.469.4418 (Phyto)

January 10, 2005

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

JAN 14 2005

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Laxative-3 Blend™	<i>Laxative-3 Blend</i> gently but effectively cleanses the intestinal surfaces and promotes bowel function without the use of harsh, stimulant laxatives, such as senna and cascara.* These laxatives chemically stimulate the intestines. If used on a routine basis, the bowels can become dependent on them and lose the built-in reflexes that normally help the bowels function. In contrast, <i>Laxative-3 Blend</i> works with the body's own elimination processes to safely promote bowel movements.*	Magnesium Hydroxide, Proprietary Mucilage Blend: slippery elm (<i>Ulmus rubra</i>) bark, marshmallow (<i>Althaea officinalis</i>) root extract and fenugreek (<i>Trigonella foenum-graecum</i>) seed extract, Proprietary Soothing Blend: peppermint (<i>Mentha x piperita</i>) leaf, fennel (<i>Foeniculum vulgare</i>) seed and ginger (<i>Zingiber officinale</i>) rhizome extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-10-05

978 0162

LET

15401

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,


Michael P. Devereux
Chief Financial Officer



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Laxative-3 Blend™	Magnesium hydroxide is an osmotic laxative that draws water into the intestinal lumen.* Fecal matter inside the intestines softens and swells, which stretches the intestinal wall and stimulates peristalsis.*	Magnesium Hydroxide

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By: _____

Robert Doster

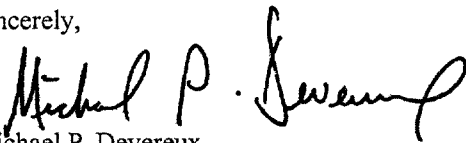
Title: Senior Vice President of Scientific Affairs

Date: _____

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Laxative-3 Blend™	Research has shown that magnesium hydroxide increases the number of bowel movements, increases percentage of stool water, and increases stool volume.*	Magnesium Hydroxide

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By: 

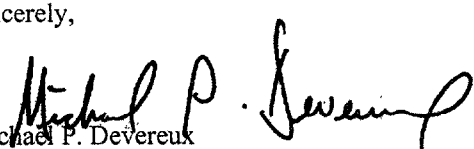
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Laxative-3 Blend™	Slippery elm (Ulmus rubra) bark has antioxidant effects and has been studied for its support of bowel health.*	Slippery elm (Ulmus rubra) bark

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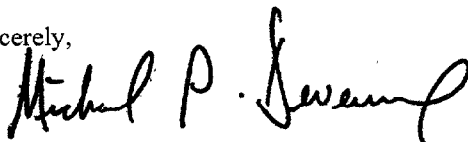
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Laxative-3 Blend™	Slippery elm (Ulmus rubra) bark has antioxidant effects and has been studied for its support of bowel health.*	Slippery elm (Ulmus rubra) bark

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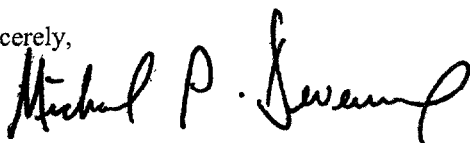
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Title: Senior Vice President of Scientific Affairs

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Laxative-3 Blend™	Marshmallow root has been studied for its support of colon mucosa.*	Marshmallow (althaea officinalis) root extract

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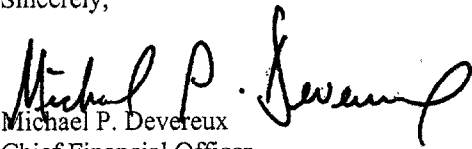
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Laxative-3 Blend™	Fenugreek has been studied for its support of gastrointestinal health.*	Fenugreek (trigonella foenum- graecum) seed extract

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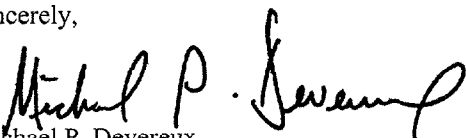
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January 12, 2005

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Laxative-3 Blend™	Peppermint (Mentha x piperita) leaf use in gastrointestinal support has been well- established.*	Peppermint (Mentha x piperita) leaf

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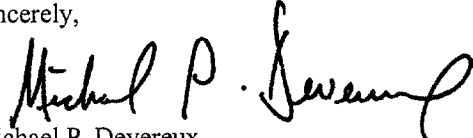
Title: Senior Vice President of Scientific Affairs

Date: _____

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Laxative-3 Blend™	Peppermint supports healthy relaxation of intestinal muscles and supports healthy bile flow.*	Peppermint (Mentha x piperita) leaf

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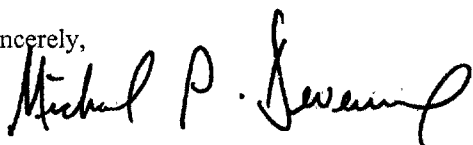
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Laxative-3 Blend™	Use of peppermint has been clinically studied for its support of gastrointestinal motility and support of healthy balanced intestinal flora.*	Peppermint (Mentha x piperita) leaf

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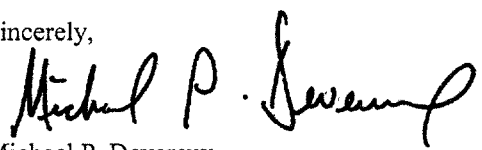
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Laxative-3 Blend™	Fennel (Foeniculum vulgare) seed also has gastrointestinal motility supportive properties.*	Fennel (Foeniculum vulgare) seed

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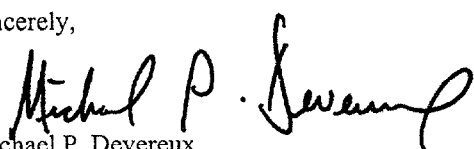
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PHYTOPHARMICA®

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P: 920.469.1313 ♦ F: 888.570.6460 (Enzymatic)
P: 920.469.9099 ♦ F: 920.469.4418 (Phyto)

January 12, 2005

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

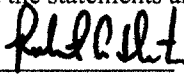
RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Laxative-3 Blend™	A recent study demonstrated fennel supports healthy relaxation of the intestinal walls.*	Fennel (Foeniculum vulgare) seed

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

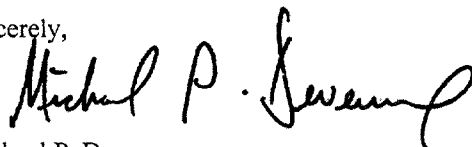
By: 
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/12/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,


Michael P. Devereux
Chief Financial Officer



ENZYMATIC THERAPY
INCORPORATED

*What **Better** feels like.™*

INTEGRATIVE THERAPEUTICS INC.™

NF Formulas ♦ PhytoPharmica
Tyler Encapsulations ♦ Vitaline Formulas

9755 SW Commerce Circle, Suite B2
Wilsonville, OR 97070
P: 503.582.8386 ♦ F: 503.582.0467

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**&
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Laxative-3 Blend™	Studies have demonstrated that ginger supports healthy intestinal tone, healthy peristalsis, and healthy secretion of gastrointestinal fluids.*	Ginger (Zingiber officinale) rhizome extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

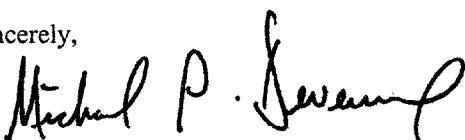
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Laxative-3 Blend™	Laxative-3 Blend is a blend of herbs and nutritional supplements designed to gently loosen built up substances on the intestinal wall and enhance the transit time of intestinal substances.* Without relying on harsh stimulants laxatives, Laxative-3 Blend provides safe and effective support for bowel elimination.*	Magnesium Hydroxide, Proprietary Mucilage Blend: slippery elm (Ulmus rubra) bark, marshmallow (Althaea officinalis) root extract and fenugreek (Trigonella foenum-graecum) seed extract, Proprietary Soothing Blend: peppermint (Mentha x piperita) leaf, fennel (Foeniculum vulgare) seed and ginger (Zingiber officinale) rhizome extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

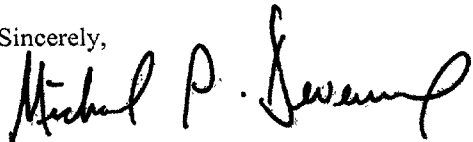
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Date: 1/12/05

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Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" being the most prominent.

Michael P. Devereux
Chief Financial Officer